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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: (510) 337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our ref: 29-51560

WARNING LETTER

September 4, 1997

Fredrick N. Hanosh, President
Implant Integration Systems, LLC
10490 San Felipe Rd.
Cupertino, CA 95104

Dear Mr. Hanosh:

We are writing to you because between July 14 and July 21, 1997, Patricia A. Cruz, an investigator from the San Francisco District of the Food and Drug Administration (FDA), conducted an inspection of your firm and determined that you manufacture dental implant accessories known as "Parallel Pins", "Depth Gauge", and "Surgical Ratchet". These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act.

Our inspection revealed that these devices are adulterated within the meaning of 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice for Medical Devices Regulation (GMP), as set forth in Title 21, *Code of Federal Regulations (CFR)*, Part 820, as follows:

1. You have not established a quality plan that defines the quality activities, resources and practices, and the applicable documentation relevant to the dental accessories manufactured by your contract manufacturer, [redacted] [21 CFR 820.20(d)].

2. The Device Master Record for the Surgical Insertion Ratchet is inadequate in that, the engineering drawing has not been signed and approved by a designated individual. Additionally, the Device Master Record for this device and for the Depth Gauge and the Parallel Pin neither includes nor refers to the location of labeling specifications and quality

assurance specifications including acceptance criteria which ensure that products will meet performance and configuration specifications such as finished and in process testing [21 CFR 820.40(a); 820.181(a), (b), (c), and(d)].

3. You have not established the controls necessary to ensure that products and services received conform to specifications. For example, you have no documents which show that your firm has evaluated [redacted] to determine whether as a contract manufacturer it is able to meet specified requirements for the dental accessories. You have not established the quality requirements that [redacted] must meet, nor have you have defined the type and extent of control to be exercised over [redacted] to ensure that it is providing devices within device specifications. Additionally, you have not established purchasing data that describes and/or references the specified requirements, including quality requirements, for the dental accessories [21 CFR 820.50(a) and (b)].

4. You have no records which show that the accessories (depth gauges, surgical insertion ratchets, and parallel pins) which are received from [redacted] are inspected according to the receiving inspection procedures outlined in your Quality Assurance Procedures [21 CFR 820.80(e)].

5. There is no statistical basis for the sampling plan used to perform incoming dimensional testing of accessories [21 CFR 820.250(a) and (b)].

We further note that the inspection also revealed the you have not validated the sterilization process which you recommend for your devices.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA-483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the GMP deficiencies are reasonably related will be cleared until violations have been corrected. Also, no requests for Certificates for Products For Export will be approved until violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration

without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to:

Andrea Scott, Compliance Officer
U.S. Food and Drug Administration
96 North Third St., Suite 325
San Jose, CA 95112

Sincerely,

Patricia C. Ziobro

Patricia C. Ziobro
District Director
San Francisco District

cc: Alan L. Hanosh, Manager